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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,644	04/06/2001	Gabriel Vogeli	00196US1/PHRM-0330	5533

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EXAMINER	
ULM, JOHN D	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,644	VOGELI, GABRIEL	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,33-90 and 93-124* is/are pending in the application.

4a) Of the above claim(s) *1-29,36-89 and 93-124* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30 31 33-35 90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1) Claims 1 to 31, 33 to 90 and 93 to 124 are pending in the instant application. Claims 30, 31, 33 and 34 have been amended and claims 91 and 92 have been canceled as requested by Applicant in the correspondence filed 10 September of 2003.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 1 to 29, 36 to 89, 93 to 124 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

5) Claims 30, 31, 33 to 35 and 90 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record as applied to claims 30, 31, 33 to 35 and 90 to 92 in section 7 of the previous office action. As essentially stated therein, the instant claims are directed to an isolated protein comprising the amino acid sequence presented in SEQ ID NO:67 of the instant application. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

Applicant has traversed this rejection on the premise that a polypeptide of the instant invention has a specific utility in the identification of ligands thereto. This is not persuasive because, as stated in the original rejection, whereas one could readily employ a putative receptor protein of the instant invention in an assay to identify ligands thereto the information obtained thereby would be of little use until one discovers the identity of those physiological processes moderated by that putative receptor". Applicant asserts that a protein of the instant invention has specific utility because it can be employed to generate antibodies thereto which can be used to detect the claimed invention *in vivo* and *in vitro*. Applicant has failed to identify any specific practical advantage that is achieved by detecting a protein of the instant invention in a sample.

Applicant urges that GPCRs, in general, are useful because antibodies to specific orphan GPCRs have been sold commercially. Applicant is advised that the selling of an item for the purpose of employing that item as the object of further research does not establish a *prima facie* utility for that compound and certainly does not establish a *prima facie* utility for any and all compounds related thereto.

Applicant has also traversed this rejection on the apparent premise that membership in the G protein-coupled receptor family is, alone, sufficient to establish a utility for a specific protein and, therefore, an assay which employs that protein. Applicant asserts that a protein of the instant invention belongs to a family of proteins of which some members are the targets of "nearly" 350 therapeutic agents currently on the market. This number is actually higher since a number of

agents such as antidepressants and hypertension medications were being employed clinically before their site of action was known. However, each clinical agent which has been developed by measuring its interaction with a specific G protein-coupled receptor was evaluated against a receptor whose native ligand and physiological function were known such as the adrenergic receptors, the dopamine receptors and the serotonin receptors. There are also numerous G protein-coupled receptors such as odorant receptors and calcium sensing receptors which do not appear to mediate any clinically significant process. More importantly. an artisan knew. before they employed a specific G protein-coupled receptor to identify clinically useful compounds, which physiological process or processes they wished to manipulate and that the protein employed in their assay had an influence of that process. Even if one identifies an agonist or antagonist for a receptor of the instant invention by employing the claimed method, this information is useless since one has no idea of what clinical effect the administration of that agonist or antagonist to an individual would have.

Applicant's reference to issued patents describing G protein-coupled receptors as establishing a patentable utility for the claimed nucleic acid is not persuasive because each application is examined on its own merits. In the decision of *In re Hutchison*, 69 USPQ 138 (CCPA, 1 946), the court held that "We are not concerned, of course, with the allowed claims in either the patent or in this application. The sole question for our determination is whether the six article claims on appeal were properly rejected below, and this we pass upon without further reference to, and without comparing them with the claims in the patent or the claims which stand

allowed in this application." In essence, the position in the instant application that each application is examined on its own merits can be found in the judicial precedent cited above. The rejections in the instant application will only be withdrawn if they are shown to be legally or factually unsound. The fact that a patent may have issued under a different fact situation or in error does not relieve the USPTO from the responsibility of preventing the reoccurrence of such errors wherever possible.

6) Claims 30, 31, 33 to 35 and 90 are rejected under 35 U.S.C. § 112. first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claims 33 and 90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. These claims require an epitope that is "specific" to SEQ ID NO:67. The instant specification discloses that the amino acid sequence presented in SEQ ID NO:67 corresponds to that of a naturally occurring member of the G protein-coupled receptor family. It is well known in the art that portions of the amino acid sequences of GPCRs tend to be highly conserved between structurally related members of that family as well as between homologous proteins from different species. Whereas one could readily produce a protein comprising an epitope from SEQ ID NO:67, one can not produce a protein comprising an epitope that is "specific" thereto because the instant specification does not identify those portions of SEQ ID NO:67 which Applicant believes

to be "specific" thereto and those portions believed to be shared with homologous and orthologous proteins.

8) Claims 31, 34, 35 and 90 are rejected under 35 U.S.C.§ 1 12. second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1) Claim 31 is confusing in reference to "a" sequence of SEQ ID NO:67 because it implies that there is more than one sequence in SEQ ID NO:67.

8.2) Claims 34 and 90 are vague and indefinite in so far as they employ the term "nGPCR-93" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "nGPCR-93" an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. Claim 35 is vague and indefinite in so far as it depends from claim 34 for this element.

8.3) Claim 34 is confusing in so far as it recites "said polypeptide comprises comprises at least one". Claim 35 is vague and indefinite in so far as it depends from claim 34 for this element.

9) Applicant's arguments filed 10 September of 2003 have been fully considered but they are not persuasive.

10) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11) This application contains claims 1 to 29, 36 to 89, 93 to 124, drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.